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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

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EDGAR R. CATAXIONS
TRASKBRITT, PC
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/627,531	BERRY ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21,23-27,29-31,33-41 and 49-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21,23-27,29-31,33-41 and 49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/06/03; 6/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and IDS filed 6/29/2006.

Claims 17-21, 23-27, 29-31, 33-41 and 49-53 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. The rejection of claims 17-21, 23-31, 33-41 and 49-53 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in view of the recitation of analogs and derivatives is withdrawn because analogs and derivatives are removed from the claims by the amendment filed 6/29/06.

4. The rejection of claims 17-21, 23-31, 33-41 and 49-53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicant's persuasive argument that it is the vehicle comprising a solvent, surfactant and polymer that is single phase and not the formulation comprising the vehicle and the beneficial agent.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 17-21, 23-27, 30, 31, 33-36, 38, 40, 41 and 49-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170)

Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) discloses compositions comprising testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA (Table 1). Testosterone is a hormone, meeting the hormone limitation of the beneficial agent in the claims. DEA and EVA meet the limitation of polymer in claims 17, 16 and 33. Lee's composition enhances the permeation of active agents through the skin and is topically administered.

Gyory discloses compositions that are delivered through the body surface in the presence of electrotransport enhancers (abstract); lauryl lactate and polysorbate and PEG-4 dilaurate are listed as electrotransport enhancers (Table 1 and column 14, lines 53, 63 and 64); testosterone, tetracaine, peptides and proteins are few of the beneficial agents that are deliverable with the electrotransport delivery device of Gyory (column 7, lines 18, 20 and 25-52). Polyvinylpyrrolidone is preferred polymer that is blended with the beneficial agent in any ratio

(column 10, lines 32-35 and 56). Testosterone is a hormone that meets the limitation of the claimed beneficial agent.

The composition of Lee enhances the transport of beneficial agents through the skin. The composition of Gyory enhances the transport of beneficial agents through the skin.

Lee discloses composition containing testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA. The composition of Lee does not contain surfactant. However, Gyory discloses a delivery vehicle that contains polymer, lauryl lactate and surfactant such as polysorbate. Regarding the selection of solvent and surfactant and polymer for a formulation that would exhibit viscosity that is capable of suspending the beneficial agent, it is noted that the skilled artisan or the person of ordinary skill is technically able, using the general teaching of Lee and/or Gyory, to formulate a composition that would be able to suspend the beneficial agent. Regarding claim 25, 26 and 31, stability of the formulation for the designated time is a property/characteristic of the formulation and a formulation/product cannot have mutually exclusive properties. Adaptation of a formulation for use in an implantable device as in claim 27 is an intended use/route of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The limitation of claims 50-53 is met by the presence of glycerol monolaurate in Lee and polysorbate surfactant in Gyory. Regarding the recited amounts of active agent, Gyory discloses that the active agent is blended with the polymer in any ratio and Lee discloses 10% testosterone meeting the limitation of the % amount recited in claims 20, 21, 34 and 35. However, there is also no demonstration in

applicants' specification showing that the amounts recited for the beneficial agents provide unusual and unexpected results. It is within the purview of the skilled artisan or the ordinary skilled practitioner to use amounts of solvent and polymer adequate for the formulation. Regarding claims 40 and 41, it is within the purview of the ordinary or skilled artisan to determine duration of treatment or effective management of the condition being treated. The skilled artisan or the ordinary person in the art is able to determine how much solvent, surfactant and polymer to use as it regards to claim 49.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lee to formulate a testosterone for enhanced topical delivery. One having ordinary skill in the art would have been motivated to combine the composition of Lee and Gyory to make a third formulation for the same purpose. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

7. Applicant's arguments filed 6/29/06 have been fully considered but they are not persuasive.

Applicant argues that the combined reference of Lee and Gyory does not "teach all of the claim limitations and, in fact teaches away from the claimed invention," because

a) the amended claims are drawn to implantable or injectable compositions including beneficial agent, that neither Lee nor Gyory, alone or in combination suggest implantable or injectable compositions since the references expressly disclose topical formulations that can "be used to enhance topical delivery of agents,"

b) the formulation of both Lee and Gyory are delivered through the skin surface,

c) Lee transdermally administers drug together with acyl lactylate permeation enhancer, which is specifically used for application to skin surfaces,

d) Gyory uses "electrotransport enhancers to permeate through the body surface and transport the beneficial agent through the skin."

Response:

Examiner interprets the new claim language to be just a formulation having an intended use. "Injectable or implantable" refers to the intended use of the formulation.

Regarding a), it is noted that the claims, even as amended, are drawn to formulations comprising non-aqueous single phase vehicle and at least one beneficial agent; the vehicle comprises a surfactant, solvent and polymer and where the solvent is lauryl lactate. The vehicle is used to deliver known beneficial agent(s). The recitation of "injectable or implantable" in the preamble conveys the intended use of the formulation. Claims 17 and 33 as amended and as presented are devoid of a device or the claims 17 and 33 as amended and presented are not drawn to devices.

The absence of specific claim to specific device precludes the formulation as claimed from assuming a specific form so that "injectable or implantable," are accorded ordinary

meanings attributed to them by those of ordinary skill in the art, which specifically defines the intended use of the formulation. "Injectable or implantable" do not define the form of the formulation as an implant or any specific device. Guidance from applicant's disclosure, for example at line 31 of page 9 to line 32 of page 12, does not provide express intent to impart a novel meaning of device limited by form to the claim terms, "injectable or implantable" and as such, these terms/words are presumed to take on the ordinary meaning of intended use. However, an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning.

The formulation of the combined references would be capable of having the same future intended use since the claimed composition in claim 17 and the combined formulation of Lee and Gyory comprises lauryl lactate, testosterone as beneficial agent (hormone), surfactant and polymer. The "injectable or implantable" does not define a device having a unique structure distinct from the formulation of the prior art.

Applicant's argument regarding b) is related to the intended use of the formulation/composition of the combined reference and topical administration of a composition does not preclude the composition from having intended use of "injectable or implantable." The claimed formulation reads on the formulation of the combined references of Lee and Gyory. Lee and Gyory does not, therefore, teach away from the invention.

Regarding c), it is noted that the comprising language of the claims is open and does not exclude the presence of the acyl lactylate. Furthermore, Lee in the background at column 1,

lines 50 and 51 states that acyl lactylate is useful as antimicrobial or antibacterial agent and would therefore not produce detrimental effect if injected or implanted with lauryl lactate containing composition.

Regarding d), it is noted that the comprising language of the claims is open and does not exclude the presence of the electrotransport enhancer. Furthermore, the electrotransport enhancers may be surfactant type agent and Gyory specifically lists sodium lauryl sulfate as one of the electrotransport enhancers (column 6, lines 2 and 8).

8. Claims 17, 29, 37 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170) and further in view of Benson et al. (US 4,078,060).

The combined formulation/composition of Lee and Gyory is described above. However, the combined formulation/composition of Lee and Gyory does not include antioxidants. But Benson discloses that testosterone can be administered parenterally, by depot injection or implantation (column 3, lines 18-54; column 4, lines 53 and 54; column 5, lines 32, 46; column 10, lines 42 and 43; Table 1); the composition can also contain antioxidant (column 6, lines 3-10). Thus Benson shows that antioxidant can be included with testosterone. Regarding implantation and parenteral administration, it is known in the art that testosterone can be administered parenterally or by implantation as disclosed by Benson.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Lee and Gyory and add antioxidant as disclosed by Benson to protect the testosterone composition form oxidation.

Response to Arguments

9. Applicant's arguments filed 6/29/06 have been fully considered but they are not persuasive.

Applicant refers to the previous argument regarding applicant's assertion that Lee and Gyory teach way from the claimed invention and further that Benson does not overcome the deficiencies of Lee and Gyory.

As discussed above, Lee and Gyory do not teach away from the invention because the amended claims are directed to formulations having future intended use. Benson, was not used to overcome the deficiencies of Lee and/or Gyory, rather, Benson is relied upon for a disclosure that antioxidant can be combined with testosterone.

Regarding parenteral administration of the claimed composition, it is noted that the formulation derived from the combined teachings of Lee and Gyory comprises lauryl lactate, surfactant and polymer and testosterone as the active agent and that the formulation comprising the testosterone can be administered topically. Benson suggests that testosterone can be administered parenterally. Thus, Benson is relied upon for suggesting parenterally administering testosterone-containing composition. Applicant has not provided factual showing that the testosterone containing formulation derived from the combined teaching of Lee and Gyory cannot be administered parenterally. Guidance/suggestion provided by Benson is that a testosterone containing composition is parenterally administrable.

NO claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600